TRANSURETHRAL NEEDLE DELIVERY DEVICE WITH CYSTOSCOPE AND METHOD FOR TREATMENT OF URINARY INCONTINENCE

This invention pertains generally to transurethral medical devices for treating urinary incontinence in humans and, more particularly, to transurethral medical devices with needles for penetrating the urethra of human females.

A large number of humans suffer from urinary incontinence, including a significant number of elderly females and nursing home residents. Stress urinary incontinence, which refers to the sudden leakage of urine with coughing, sneezing, exercise or activities that increase intra-abdominal pressure, most commonly occurs in women following childbearing or in men following prostatic surgery. Procedures have heretofore been provided for treating urinary incontinence. However, none of these modalities have proven to be optimal in all cases. There is, therefore, a need for a device and method for treating urinary incontinence which overcomes these disadvantages.

In general, it is an object of the present invention to provide a device and method for the treatment of urinary incontinence.

Another object of the invention is to provide a device and method of the above character in which an agent is introduced into tissue surrounding the urethra to add support to the sphincter muscle.

Another object of the invention is to provide a device and method of the above character in which the agent is introduced into a void in the tissue.

Another object of the invention is to provide a device and method of the above character in which the agent is introduced into a void created in the tissue by radio frequency ablation.

Another object of the invention is to provide a device and method of the above character in which the agent is heated during introduction into the tissue to prevent solidification of the agent prior to introduction.

Another object of the invention is to provide a device and method of the above character in which the agent is heated after its introduction into the target volume of tissue to facilitate solidification of the agent therein.

Another object of the invention is to provide a device and method of the above character in which the agent is heated after its introduction into the target volume by applying radio frequency energy thereto.

Another object of the invention is to provide a device and method of the above character in which the agent is simultaneously introduced into a plurality of target volumes within tissue surrounding the urethra.

Additional objects and features of the invention will appear from the following description from which the preferred embodiments are set forth in detail in conjunction with the accompanying drawings.

FIG. **1** is a perspective view of an embodiment of the transurethral needle delivery device of the present invention.

FIG. **2** is a cross-sectional view of the transurethral needle delivery device of FIG. **1** taken along the line **2—2** of FIG. **1**.

FIG. **3** is a cross-sectional view of the transurethral needle delivery device of FIG. **1** taken along the line **3—3** of FIG. **2**.

FIG. **4** is a cross-sectional view of the transurethral needle delivery device of FIG. **1** taken along the line **4—4** of FIG. **3**.

FIG. **5** is an enlarged isometric view, partially cut away, of the transurethral needle delivery device of FIG. **1** taken along the line **5—5** of FIG. **2**.

FIG. **6** is an illustration of a portion of the transurethral needle delivery device of FIG. **1** in place within the urethra of a female human body.

FIG. **7** a perspective view of another embodiment of the transurethral needle delivery device of the present invention.

FIG. **8** is a cross-sectional view of the transurethral needle delivery device of FIG. **7** taken along the line **8—8** of FIG. **7**.

FIG. **9** is a cross-sectional view of the transurethral needle delivery device of FIG. **7** taken along the line **9—9** of FIG. **8**.

FIG. **10** is an illustration of a portion of the transurethral needle delivery device of FIG. **7** in place within the urethra of a female human body.

In general, a medical device is provided for use in a female human body to deliver an agent to a target volume of tissue surrounding a urethra in the body. The tissue includes a sphincter muscle and the urethra is formed by a urethral wall extending from a bladder to the exterior of the body. The device includes an elongate probe member having proximal and distal extremities and a longitudinal axis. The elongate probe member is sized to be able to enter the urethra and has a length so that when the distal extremity is disposed in the vicinity of the target volume of tissue the proximal extremity is outside of the urethra. The elongate probe member has a passage extending from the proximal extremity to the distal extremity. At least one tubular needle is disposed in the passage and has first and second extremities and a flow passageway therein extending longitudinally from the first extremity to at least one opening provided in the second extremity of the at least one tubular needle. A control handle is secured to the proximal extremity of the elongate probe member. Operative means is carried by the control handle and is connected to the first extremity of the at least one tubular needle for causing movement of the at least one tubular needle in the passage. Means is carried by the elongate probe member for causing movement of the at least one tubular needle through a curved path extending at an angle to the longitudinal axis. Means is carried by the proximal extremity of the elongate probe member and in communication with the flow passageway of the at least one tubular needle for introducing the agent into the flow passageway. When the at least one tubular needle is advanced through the urethral wall under the control of the operative means at least the opening in the second extremity of the tubular needle has been advanced into the target volume to permit the agent to be introduced through the flow passageway and opening in the tubular needle into the target volume so as to add support to the sphincter muscle.

A method is provided to deliver an agent to a target volume of tissue surrounding a urethra in a human body. The tissue includes a sphincter muscle and the urethra is formed by a urethral wall extending from a bladder to the exterior of the body. The method includes the step of advancing a tubular needle having a free extremity with at least one opening therein into tissue surrounding the urethra wall so that the opening is in the target volume. The agent is introduced into the target volume so as to add support to the sphincter muscle.

More in particular, transurethral needle delivery medical device **20** of the present invention is for use in treating urinary incontinence, specifically stress urinary incontinence in females. In this regard, device **20** can be utilized to inject a suitable agent or medication such as a compound **21** into the tissue surrounding the urethra immediately above and below the sphincter urethrae muscle. Delivery device **20** illustrated in FIGS. **1–5** includes an up to 26 French catheter-